A final order reclassifying shortwave diathermy (SWD) intended for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue by means other than the generation of deep heat within body tissues, a preamendments Class III device, into class II, and renaming the device "nonthermal shortwave therapy" (SWT), was published on October 13, 2015. See here: https://www.federalregister.gov/documents/2015/10/13/2015-25923/physical-medicine-devices-reclassification-of-shortwave-diathermy-for-all-other-uses-henceforth-to

While the device submitted and cleared through K091791 may serve as a valid predicate device for a new SWT device, please refer to the aforementioned final order for current regulatory requirements for this device type.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Regenesis Biomedical, Inc.
% Mr. William H. Quirk
755 East Mulberry Avenue
Suite 200
San Antonio, TX 78212

Re: K091791
Trade/Device Name: Provant System
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave diathermy
Regulatory Class: III
Product Code: ILX
Dated: April 1, 2010
Received: April 6, 2010

APR 07 2010

Dear Mr. Quirk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

Indications for Use

510(k) Number (if known): K091791

Device Name: **Provant System**

INDICATIONS FOR USE:

The Provant System is intended for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091791

510(k) Summary

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.
Submitter	Regenesis Biomedical, Inc.
Contact Person	William H. Quirk 755 E. Mulberry, Suite 200 San Antonio, Texas 78212 (210) 240-9881
Date Prepared	10 June 2009
Product Name	Provant System
Common Name	Short-wave diathermy device
Device Classification	Class III
Predicate Device(s)	Regenesis Model 42
Performance Standards	Performance standards have not been established by the FDA under section 514 of the Federal, Food, Drug and Cosmetic Act.
Device Description	Much like the predicate Regenesis Model 42 device, the new Provant System includes a Control Unit and Treatment Applicator. Disposable Applicator Covers are provided for the Treatment Applicator for infection control and to provide appropriate contact surfaces for the patient. The predicate Provant System contains the same components. The Control Unit for the Provant System is housed in a UL-compliant injection-molded case made of high-impact ABS plastic. The case contains a lockable hinge to prevent accidental closure of the lid. Upon opening the Provant case, the user sees the control panel of the Control Unit. The main electronics of the Control Unit are housed beneath its control panel. The device also includes a Treatment Applicator that is attached to the Control Unit.

Device Description (continued)	When not in use, the Treatment Applicator is stored inside the carrying case. The Treatment Applicator is removed from the case prior to administration of therapy, inserted into its Disposable Applicator Cover, and placed directly over the area to be treated. Device labeling is also located inside the case cover. Four pre-drilled holes in the underside of the case allow for attachment of the device to the optional roller stand (sold separately). The Disposable Applicator Covers of the Provant System are single-use-only and are intended to minimize contagion and help protect the Treatment Applicator from biological contamination. The Disposable Applicator Covers contain a Radio Frequency Identification Device (RFID) tag which guards against reuse of used Disposable Applicator Covers.
Indications for Use	The Provant System and its predicate are both intended for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue.
Technological Characteristics	Both the Provant System and the predicate device use shortwave radio frequency energy to treat postoperative superficial pain and edema. The proposed Provant System has similar features and technological characteristics as the predicate.
Nonclinical Performance	Bench testing data demonstrates that the technological differences between the Provant System and its predicate do not raise new questions of safety or effectiveness. These data also demonstrate that the Provant System delivers the same amount of energy to the subject and is therefore as safe and as effective as its predicate.
Clinical Data	Although the reusable portions of the Provant System have extensive clinical experience, this 510(k) Notice does not rely upon clinical data.
Conclusion	The Provant System and the predicate device have the same intended use and similar technological characteristics. The results of bench testing further demonstrate that the Provant System does not raise any new questions of safety or effectiveness as compared to its predicate device. Thus, the Provant System is substantially equivalent to its predicate device.